No. 84-162

# In the Supreme Court of the United States

OCTOBER TERM, 1984

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AN ARTICLE OF DEVICE: "TOFTNESS RADIATION DETECTOR," ET AL., PETITIONER

*v.*

UNITED STATES OF AMERICA

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*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT*

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## MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

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## TABLE OF AUTHORITIES

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In this misbranding case under the Federal Food, Drug, and Cosmetic Act, petitioners challenge the ruling of the courts below that a party claiming entitlement to the prescription device exemption has the burden of proving all elements of the exemption, including the effectiveness of the device.

1. The Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 301 *et seq.*, authorizes the United States to seize and condemn misbranded medical devices. 21 U.S.C. 321(h), 334(a). A device is "misbranded" unless its labeling bears "adequate directions for use." 21 U.S.C. 352(f). The Act authorizes

the Secretary of Health and Human Services to promulgate regulations defining exemptions from the misbranding provision (*ibid.*) and otherwise providing for efficient enforcement of the Act. 21 U.S.C. 371(a).

The Secretary's regulations interpret "adequate directions for use" to mean directions that a lay person can follow. 21 C.F.R. 801.5. This interpretation was codified in 1952 (17 Fed. Reg. 6818), and has been consistent since passage of the Act in 1938. See *United States* v. *Articles of Drug*, 625 F.2d 665, 672 (5th Cir. 1980). An exemption from this lay standard of labeling is provided for prescription devices. 21 C.F.R. 801.109. The exemption includes a condition that the medical device be safe and effective when used by a practitioner. 21 C.F.R. 801.109(c).

2. The Toftness Radiation Device (TRD) is a plastic cylinder containing a series of lenses (Pet. App. 2). The proponents of the TRD claim that a chiropractor trained in its use can detect low level electromagnetic radiation emanating from a patient's body and thereby diagnose areas of neurological disturbance (*ibid.*).

The United States brought this action to condemn the TRD and enjoin its further use because it was "misbranded" within the meaning of the Act (21 U.S.C. 352(f)(1)). The district court found that the government had established misbranding as a matter of law by proving that the TRD was a device in interstate commerce that lacked adequate directions for use by a lay person (Pet. App. 23-24). The court instructed the jury that it was to find the TRD misbranded unless it concluded that the device qualified for an exemption from the Act's labeling

requirements (*id.* at 24). For the TRD to be exempt as a prescription device, petitioners thus would be required to carry the burden of proving its effectiveness (*id.* at 25). The district court entered judgment on the jury's general verdict for the government (*id.* at 34-37).

The court of appeals affirmed (Pet. App. 1-20). The court determined that the prescription device regulation is framed as an exemption from the labeling requirements and that this regulatory structure is consistent with the Act (*id.* at 14-16). In sustaining the district court's allocation of the burden of proof, the court relied (*id.* at 15-17) on this structure and on the government's disadvantage in gaining access to evidence on the issue of effectiveness. The court noted, for example, that in the present case petitioners attacked the testimony of government experts, who found the TRD to be "completely worthless in diagnosis," by arguing that the government experts lacked the special training available only at the Toftness Post-Graduate School of Chiropractic, Inc. (*id.* at 17).

3. The court of appeals' decision is correct and does not conflict with any decision of this Court or any other court of appeals. Further review is therefore unwarranted.

The court of appeals used two established criteria for determining how to allocate the burden of proof. First, a party claiming an exemption from a statutory requirement ordinarily must prove entitlement to the exemption. See *United States* v. *First City National Bank*, 386 U.S. 361, 366 (1967). Second, the burden of proof is usually on the party with better access to the relevant evidence. See *United States* v. *New York, N.H. & H.R.R.*, 355 U.S. 253, 256 (1957).

Petitioners do not dispute the soundness of these principles. Nor do they contest the court of appeals' conclusion that evidence regarding the effectiveness of prescription devices such as the TRD is generally more accessible to the manufacturer or distributor than to the government. Petitioners' sole argument is based on the other ground of the court of appeals' decision, *i.e.*, that petitioners should bear the burden of proof because they were claiming entitlement to the regulatory exemption for prescription devices (21 C.F.R. 801.109). Petitioners maintain that the regulations should have required the government to prove that prescription devices do not bear adequate directions for use, rather than requiring the manufacturer or distributor to prove entitlement to the exemption.

Petitioners' argument completely misconstrues the standards under which regulations are judged. The Secretary is authorized "to promulgate regulations for the efficient enforcement of [the Act]" (21 U.S.C. 371(a)). Thus, unless Congress has "directly addressed the precise question at issue," the proper inquiry is "whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984), slip op. 4-5. Moreover, the Secretary's judgment regarding the structuring of exemptions is entitled to particular deference in view of its long-standing character. *CBS, Inc.* v. *FCC*, 453 U.S. 367, 382 (1981). Cf. *NLRB* v. *Transportation Management Corp.*, No. 82-168 (June 15, 1983), slip op. 4-11 (noting discretion of NLRB to determine allocation of burden of proof). Here, the challenged regulation is plainly valid because it is "not contrary to either the letter or intent of the statute" (Pet. App. 16)

and is amply justified by the government's disadvantageous access to evidence regarding effectiveness.

The only authority petitioners offer for their position is *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981). Petitioners concede that references to the burden of proof in that case were dicta (Pet. 13). Neither the district court (Pet. App. 26 n.2) nor the court of appeals (*id.* at 13 n.4) had any trouble distinguishing *Evers*. A "passing comment" (Pet. App. 13 n.4) such as the one in that case does not create a conflict necessitating review by this Court.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

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